REMARKS

Claims 1, 3-8, 10-12, 14-32, 34-35, and 37-42 are pending in the subject application. By this Amendment, claims 1, 26, and 37-41 are amended in order to place the subject application in better condition for appeal. Support for the claim amendments is provided in the originally-filed application, and Applicant respectfully submits that no new matter is presented herein.

Entry of this Amendment is proper under 37 C.F.R. § 1.116 since this Amendment: (a) places the application in condition for allowance for reasons discussed herein; (b) does not raise any new issue regarding further search and/or consideration since the Response amplifies issues previously discussed throughout prosecution; (c) does not present any additional claims without canceling a corresponding number of finally-rejected claims; and (d) places the application in better form for appeal, should an appeal be necessary. The Amendment is necessary because it is made in reply to arguments raised in the rejection. Entry of this Amendment is therefore respectfully requested.

Rejection under 35 U.S.C. § 112

Claim 42 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action took the position that claim 42 recites subject matter not disclosed in the specification. In particular, the Office Action took the position that the feature wherein "the weight ratio of said one, or more than one hydrodynamic fluid-imbibing polymer to said one, or more than one hydrostatic pressure modulating agent is from about 35:1 to about 167:1; and the weight ratio of said one, or more than one hydrodynamic fluid-imbibing polymer to said agent of interest is from about 1:1 to about 9:1", is not disclosed in the specification. *See* page 9, paragraph 9 of the Office Action.

Applicant submits that this feature is disclosed in the specification as originally filed, at least in Tables 1-7 of Examples 2-8. The following table, which was also provided in Applicant's November 30, 2005 Amendment & Response, lists the amount of the hydrodynamic fluid-imbibing polymer(s) ("A"), the amount of the hydrostatic pressure modulating agent(s) ("B"), and the amount of the active agent ("C") provided in each of Examples 2-8, as well as the values of A/B and A/C, which have been calculated using the amounts of A, B, and C in each example.

	Example Number						
Component (mg)	**2**	**3**	**4**	**5**	**6**	**7**	**8**
A: Hydrodynamic Fluid-Imbibing Polymer(s)	Carbopol® 971P (280 mg)	Carbopol® 971P (320 mg)	Carbopol® 971P & Carbopol® 934P (total = 180 mg)	Carbopol® 971P (171 mg)	Carbopol® 971P (171 mg)	Carbopol® 971P (203.7 mg)	Carbopol® 971P (200.5 mg)
B: Hydrostatic Pressure Modulating Agent	Crospovidone XL-10 (8 mg)	Crospovidone XL-10 or INF-10 (6.4 mg)	Crospovidone XL-10 or INF-10 (3.6 mg)	Crospovidone XL-10 or INF-10 (3.6 mg)	Crospovidone XL-10 or INF-10 (3.6 mg)	Crospovidone XL-10 (1.54 mg)	Crospovidone XL-10 (1.2 mg)
C: Active Agent	Caffeine (70 mg)	Theophylline (80 mg)	Nifedipine (60 mg)	Diltiazem (60 mg)	Buspirone HCl (20 mg)	Ranitidine HCl (60 mg)	Tramadol HCl (200 mg)
A:B	35:1	50:1	50:1	47.5:1	47.5:1	132:1	167:1
A:C	4:1	4:1	3:1	2.8:1	8.6:1	3.4:1	1:1

In view of this disclosure provided in the specification, Applicant submits that the rejected features of claim 42 are fully supported therein, and respectfully requests withdrawal of this rejection.

The Claimed Invention

The present invention relates to hydrostatic delivery systems including a homogenous mixture of a hydrostatic couple that includes a hydrodynamic fluid-imbibing polymer and a hydrostatic pressure-modulating agent, and an agent of interest. The agent of interest is released in a controlled manner with zero-order or near zero-order release kinetics.

Applicant respectfully submits that none of the cited references disclose or suggest ***a hydrostatic delivery system comprising a homogenous mixture of a hydrostatic couple and an agent of interest that provides zero-order or near zero-order release kinetics***. The hydrostatic delivery systems of the claimed invention provide controlled release of an agent of interest contained within the delivery system, using non-osmotic hydrostatic differential pressure. *See* Applicant's specification, page 10, lines 15-17.

Rejections under 35 U.S.C. §§ 102(b) and 103(a)

In the outstanding Office Action, the claims have been rejected using references that do not disclose or suggest all of the features of the claims described above.

The outstanding Office Action rejected claims 1, 3-5, 7-8, 10, and 38-39 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,357,636 (Dresdner, Jr. et al.). Claims 1, 3-8, 10-12, 14-32, 34-35, and 40-41 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,582,838 (Rork et al.) and U.S. Patent No. 5,780,057 (Conte et al.). Claims 37 and 42 were not rejected based on prior art, but the Office Action did not indicate that these claims contain allowable subject matter.

Applicant respectfully traverses the outstanding rejections, and submits that they were made in error for at least the reasons set forth below. Applicant requests that these erroneous rejections be withdrawn, and that the pending claims be allowed.

Rejection under 35 U.S.C. §102(b) over Dresdner, Jr. et al.

Claims 1, 3-5, 7-8, 10, and 38-39 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,357,636 (Dresdner, Jr. et al.).

Dresdner, Jr. et al. relates to a flexible glove including an antiseptic composition provided between inner and outer glove layers. The antiseptic composition may include viscosity modifiers, such as Carbopol (which is an acrylic acid polymer cross-linked with allylsucrose or allylpentaerythritol) and cross-linked polyvinylpyrrolidone. The antiseptic composition may also include antiseptics such as sodium perborate and sodium hypochlorite. The glove disclosed in Dresdner, Jr. et al. provides "automatic" and "immediate" release of the antiseptic composition upon being punctured, *i.e.*, it exhibits first-order release kinetics. *See, e.g.*, col. 13, lines 34-39; col. 14, lines 32-37; col. 14, lines 50-53; col. 15, lines 7-10; col. 20, line 65 to col. 21, line 1; col. 21, lines 11-14; col. 21, line 65 to col. 22, line 3.

The Office Action takes the position that Dresdner, Jr. et al. discloses the composition of claims 38 and 39, and that Applicant has allegedly recognized this. Applicant emphatically disagrees with this characterization. Applicant wishes to point out that although the Amendment dated August 28, 2006 recognized that Dresdner, Jr. et al. discloses a composition containing Carbopol and/or cross-linked polyvinylpyrrolidone as

viscosity modifiers, and sodium perborate and sodium hypochlorite as antiseptics, Applicant ***did not*** indicate that Dresdner, Jr. et al. discloses the claimed hydrostatic delivery systems.

Inclusion of a few common ingredients, used in a different application for a different purpose, does not establish that Dresdner, Jr. et al. discloses the hydrostatic delivery systems of the claimed invention. In fact, there is absolutely no teaching whatsoever in Dresdner, Jr. et al. of anything in any way applicable to hydrostatic delivery systems, hydrostatic couples, dosage forms providing zero-order or near zero-order release kinetics, or anything in any way related to the claimed invention.

Under U.S. patent practice, a reference must teach every element of a claim in order to properly anticipate the claim under 35 U.S.C. § 102. In addition, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). "Every element of the claimed invention must be arranged as in the claim . . . specifically, the identical invention must be shown in as complete detail as contained in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). Further, when determining the patentability of a claim, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970); *see also* M.P.E.P. § 2143.03. None of these requirements for anticipation is met in the outstanding rejection based on Dresdner, Jr. et al.

Both the established case law and the features of claims 1, 3-5, 7-8, 10, and 38-39 have been ignored in order to maintain the rejection based on Dresdner, Jr. et al. Dresdner, Jr. et al. does not disclose or suggest at least a hydrostatic delivery system comprising a homogenous mixture of a hydrostatic couple and an agent of interest, where the agent of interest is released in a controlled manner with zero-order or near zero-order release kinetics. Accordingly, Dresdner, Jr. et al. does not anticipate claims 1, 3-5, 7-8, 10, and 38-39, nor are claims 1, 3-5, 7-8, 10, and 38-39 obvious in view of Dresdner, Jr. et al. Applicant therefore respectfully requests that this rejection be withdrawn.

Rejection under 35 U.S.C. § 103(a) over Rork et al. and Conte et al.

Claims 1, 3-8, 10-12, 14-32, 34-35, and 40-41 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,582,838 (Rork et al.) and U.S. Patent No. 5,780,057 (Conte et al.).

Rork et al. relates to a multi-layer tablet composition in which a core comprises at least two layers, where one layer includes an active agent and a polymer that forms microscopic gel beads when hydrated, and a second layer includes a polymer that forms microscopic gel beads when hydrated. An impermeable coating adheres to and surrounds the core, and contains apertures that provide an area for hydration and release of microscopic gel beads. The combination of the impermeable coating and the multiple layers having different compositions permit control over when the active agent is released.

Conte et al. relates to a multi-layer tablet composition including at least two layers. The dosage forms are designed to provide controlled release of active ingredients that are only absorbed in the stomach, duodenum, and the first portion of the small intestine. At least one layer contains a polymer that can rapidly swell on contact with fluids, thereby increasing the tablet volume, and increasing the residence time of the pharmaceutical in the stomach. Another layer contains the active agent and a polymer. The swellable layer and an optional third layer may be impermeable to the active agent, and may form barriers that modulate the release of the active agent.

Under U.S. patent practice, to establish a *prima facie* case of obviousness, each of the following three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine their teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. *See* M.P.E.P. § 2142.

No proper motivation has been provided to combine and modify the disclosures of Rork et al. and Conte et al. in the manner suggested in the Office Action. Applicant submits that one skilled in the art would not be motivated to combine and modify their teachings to arrive at the claimed invention, because both Rork et al. and Conte et al. rely upon one or more separate polymeric layers provided in their dosage forms to provide the desired controlled release of the active agent contained in a separate layer. Omitting these multiple layers and providing a homogenous composition would render both Rork et

al. and Conte et al. unsuitable for their intended uses and change their principles of operation, and this modification is therefore improper. Further, nothing in the disclosures of either of Rork et al. or Conte et al., or any other reference, would suggest the desirability of the proposed modification.

One skilled in the art would also conclude that there is not a reasonable expectation of success in making the proposed modifications to Rork et al. and Conte et al., because neither of these references provides any guidance whatsoever regarding preparing a hydrostatic delivery system that includes a homogenous mixture of an agent of interest and a hydrostatic couple.

Further, even if combined, Rork et al. and Conte et al. still fail to disclose or suggest a hydrostatic delivery system comprising a homogenous mixture of a hydrostatic couple and an agent of interest.

In view of the above, Applicant respectfully submits that Rork et al. and Conte et al., alone or in combination, fail to disclose or suggest the all features of the pending claims, and that the Office Action has failed to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a) with respect to claims 1, 3-8, 10-12, 14-32, 34-35, and 40-41. As such, Applicant respectfully requests that the rejection of claims 1, 3-8, 10-12, 14-32, 34-35, and 40-41 as allegedly being unpatentable over Rork et al. and Conte et al. be withdrawn.

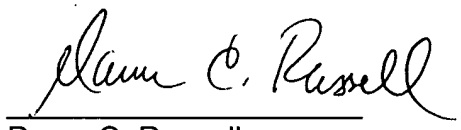
CONCLUSION

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of Claims 1, 3-8, 10-12, 14-32, 34-35, and 37-42, and the prompt issuance of a Notice of Allowability are respectfully solicited.

Should the Examiner believe anything further is desirable in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event this paper is not considered to be timely filed, Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to counsel's Deposit Account No. 01-2300, **referencing Attorney Dkt. No. 026806.00017**.

Respectfully submitted,



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